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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,557	08/22/2001	Erik Gunther	GUNE117293	8854

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EXAMINER
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CLOW, LORI A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/935,557

Applicant(s)

GUNTHER, ERIK

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-25 and 32-37 is/are pending in the application.
- 4a) Of the above claim(s) 12-17 and 22-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-11, 18-21, and 32-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

Applicants' response, filed 13 July 2006, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 14, 6-11, 18-21, and 32-37 are currently pending. Claims 5, and 26-31 have been cancelled. Claims 12-17 and 22-25 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10 October 2003.

**Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 6-11, 18-21, and 32-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "specific therapeutic activity". It is unclear, however, for what or to what the therapeutic activity is specific. For example, is the "specific" activity targeted to a particular disease or disorder? Is the activity "specific" to or for a therapy? Clarification is requested.

Claim 2 recites "one or more candidate analytes". It is unclear if these are intended to be the "analytes that induce a third expression profile" as recited in claim 1 or if these are different analytes, as "candidate analyte" is not recited in claim 1. Clarification is requested.

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Claims 3 and 33 recite “wherein step (d) is accomplished”. It is unclear if this is intended to replace the comparison in step (d) or if step (d) is further limited to classify the profiles. What is the relationship between classifying the expression profiles and the other method steps that “identify analytes”? Clarification is requested.

Claims 4, 9, 11, 18, 34, and 36 recite “is determined”. It is unclear whether this is intended to be a limitation of the data or a limitation of the method (i.e. the assays). If this is a limitation of the method, then what active method step is intended? Clarification is requested.

Claim 7 recites “at least one biological sample is derived from a disease state”. It is unclear if Applicant intends that the sample be derived from a sample that is taken from a subject with a disease or if Applicant intends that the sample be derived from a “state”. Clarification is requested.

Claim 10 recites “wherein the polynucleic acid microarrays differentially bind specific peptides”. It is unclear whether this is intended to be a limitation of the microarrays (i.e. they must be capable of differential binding) or if this a limitation of the method step (e.g. a step of differentially binding). If this is a limitation of the method, is this intended to limit an assay or something else? Clarification is requested.

Claims 19 and 37 recite “wherein step (c) is conducted many times”. It is unclear if Applicant intends that the step performed many times is the treatment (i.e. the assay itself is repeated with a single analyte) or if similar assays are run with different analytes as the “treatment”. Clarification is requested.

Claim 20 recites “the first expression profile of step (a) is derived from”. It is unclear whether this is intended to be a limitation of the data or a limitation of the method (i.e. the

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assays). If this is a limitation of the method, then what active method step is intended?

Clarification is requested.

Claim 32 recites “sample differs from the first biological sample by a drug treatment”. It is unclear what is intended by this limitation. Does Applicant intend that the second sample is a sample that has been treated with a drug or one which IS a drug “treatment”? Clarification is requested.

Claim 32 recites “specific pharmacological activity with respect to the drug treatment”. It is unclear what relationship is intended by “with respect to a drug treatment”. Does Applicant intend that the third sample also be treated with the drug or that the third sample differ from the second, which has been treated with a drug? Clarification is requested.

### **Conclusion**

No claims are allowed.

The outstanding rejections under 35 USC 101 have been withdrawn in view of Applicant's amendments to the claims.

### **Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

September 29, 2006

Lori A. Clow, Ph.D.

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*Lori A. Clow*

MARJORIE A. MORAN

PRIMARY EXAMINER

*Marjorie A. Moran*  
10/2/06